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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/974,798

10/12/2001

Ellen M. Heath

770047.402

7769

500 7590 08/11/2009  
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EXAMINER

OLSON, ERIC

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

08/11/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/974,798	<b>Applicant(s)</b> HEATH ET AL.	
	<b>Examiner</b> ERIC S. OLSON	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on June 4, 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-32,34-36,38-43,45-59,61-63 and 65-71 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-32,34-36,38-43,45-59,61-63 and 65-71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**Detailed Action**

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 4, 2009 has been entered.

This office action is a response to applicant's communication submitted June 4, 2009 wherein claims 21, 23, 32, 36, 40, 45, 49, 53, 59, 63, and 67 are amended. This application was filed October 12, 2001 and makes no priority claims.

Claims 21-32, 34-36, 38-43, 45-59, 61-63, and 65-71 are pending in this application.

Claims 21-32, 34-36, 38-43, 45-59, 61-63, and 65-71 as amended are examined on the merits herein.

Applicant's terminal disclaimer, submitted June 4, 2009, disclaiming the terminal portion of any patent issued on this application extending beyond the expiration of any patent issued on US application 11/589364, has been accepted and entered into the record. This terminal disclaimer is persuasive to overcome the rejection of instant claims 21-32, 34-36, 38-43, 45-59, 61-63, and 65-71 under the doctrine of obviousness-

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type double patenting for claiming the same invention as claims 1-85 of 11/589364.

Therefore the rejection is withdrawn.

Applicant's arguments, submitted June 4, 2009, with respect to the rejection of instant claims 21-26, 30-32, 34-36, 38-40, 42, 43, 45-53, 57-59, 61-63, 65-67, and 69-71 under 35 USC 103(a) for being obvious over Deggerdal et al. in view of Lader, have been fully considered and found to be persuasive to remove the rejection as Lader discloses high concentrations of lithium chloride in a storage medium which is distinct from an extraction medium and does not possess a pH of greater than 7 or a nonionic detergent. Therefore the rejection is withdrawn.

Applicant's arguments, submitted June 4, 2009, with respect to the rejection of instant claims 41 and 68 under 35 USC 103(a) for being obvious over Deggerdal et al. in view of Lader in view of Calbiochem, have been fully considered and found to be persuasive to remove the rejection as Lader discloses high concentrations of lithium chloride in a storage medium which is distinct from an extraction medium and does not possess a pH of greater than 7 or a nonionic detergent. Therefore the rejection is withdrawn.

Applicant's arguments, submitted June 4, 2009, with respect to the rejection of instant claims 27-29 and 54-56 under 35 USC 102(a) for being obvious over Deggerdal et al. in view of Lader in view of Heath et al., have been fully considered and found to be

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persuasive to remove the rejection as Lader discloses high concentrations of lithium chloride in a storage medium which is distinct from an extraction medium and does not possess a pH of greater than 7 or a nonionic detergent. Therefore the rejection is withdrawn.

The following rejections of record in the previous action are maintained:

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21-27, 30-32, 34-36, 38-40, 42, 43, 45-54, 57-59, 61-63, 65-67, and 69-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deggerdal et al.

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(PCT international publication WO96/18731, of record in previous office action) in view of Nargessi. (US patent 6855499, of record in previous action).

Deggerdal et al. discloses a method of isolating a nucleic acid, including RNA, by treating the nucleic acid with detergent and allowing it to bind to a solid support. (p. 5, paragraphs 2-4) The nucleic acid can be isolated from any material containing nucleic acids, including the microorganisms, clinical samples, and environmental samples described in instant claims 23-26 (p. 6, paragraphs 2-3) including plant cells, mycoplasmas, protozoa, bacteria, fungi, and viruses, for example, and can include semi-pure materials as described in instant claim 21. The binding step can be preceded by a lysing step to lyse the biological material. (p. 6, last paragraph) Detergents suitable for use in this invention include any detergent, including non-ionic detergents. (p. 7, last paragraph) Additionally, a source of monovalent cations in a concentration of 0.1-1M can be included to increase nucleic acid capture (p. 8, second paragraph) along with a chelating agent such as EDTA. (p. 8, third paragraph) Several examples are provided of lysis solutions in which the monovalent cation is LiCl of up to 0.5M and the solution is buffered at pH 7.5, which is greater than 7. (p. 8, bottom of page) The solid support can be made of any well known solid support material, including non-silica materials such as glass, latex, or a polymeric material, and can be in various physical forms including tubes, plates, or wells. (p. 9, paragraphs 2-3) More than one solid support can be used. (p. 13, second paragraph) After the lysis and binding steps, washing and elution steps can be further performed to wash and isolate the nucleic acid. (p. 12, paragraphs 2-4) Examples are given in which all of the steps (a)-(e) of instant claim 21 are performed,

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for example, example 1 on p. 19. Binding is described to take place in a micorcentrifuge tube in example 6. (p. 23, lines 20-26)

Deggerdal et al. does not disclose a method in which lithium chloride is included in the lysis solution at a concentration of 4-10M or a method using cellulose as the solid support.

Nargessi discloses a method whereby nucleic acids are induced to absorb to a paramagnetic solid support such as paramagnetic cellulose-coated beads. (column 1, lines 45-52) Adsorption to solid support is facilitated by high concentrations of polyethylene glycol and salts. (column 1, lines 64-67) Salts useful in this method include various alkali and alkaline earth metal chlorides such as lithium chloride. (column 4, lines 8-12) Generally, the salt can be present in up to about 5M. (column 4 lines 19-20)

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Deggerdal et al. by using a cellulose solid support for the purification and by adding 4-5M of lithium chloride to the lysis/binding buffer. One of ordinary skill in the art would have been motivated to modify the invention in this manner because Nargessi discloses that these concentrations of lithium chloride facilitate the binding of nucleic acid to the solid support, and because Nargessi explicitly suggests using cellulose as the solid support in the purification procedure. One of ordinary skill in the art would reasonably have expected success because adjusting the concentration of one component of a known mixture within the range disclosed by the prior art (i.e. choosing the upper range of 4-5M from the broad range of 0.25-5M) is within the ordinary and routine skill in the art. Moreover, the claimed ranges "overlap or

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lie inside ranges disclosed by the prior art” a *prima facie* case of obviousness exists.

See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 2144.05 [R-1].

Therefore the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant’s arguments, submitted September June 4, 2009, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that Deggerdal et al. teaches away from combination with Nargessi because Deggerdal et al. teaches that increased viscosity (i.e. from DNA contamination) is undesirable in preparation, and the method of Nargessi requires adding polyalkylene glycol to the sample. However, Deggerdal’s statements regarding increased viscosity from DNA contamination relate to problems with sample handling in purified samples of RNA. By contrast, the method of Nargessi does not introduce polyalkylene glycol into the final purified sample, but rather uses it in the binding and wash buffers. These buffers are used only to load the sample onto the solid phase and wash the solid phase, and are not present in the final purified sample. For example, examples 1-16 in columns 6-13 of Nargessi, the nucleic acid is eluted from the column using either deionized water or TE buffer. Neither of these elution buffers contain polyalkylene glycol or any other viscosity increasing agent. Therefore one of ordinary skill in the art would have recognized that the polyalkylene glycols used in the method of Nargessi do not remain in the sample, and the product would not be undesirably viscous.



Claims 41 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deggerdal et al. (PCT international publication WO96/18731, of record in previous office action) in view of Nargessi. (US patent 6855499, of record in previous action) as applied to claims 21-27, 30-32, 34-36, 38-40, 42, 43, 45-54, 57-59, 61-63, 65-67, and 69-71 above, and further in view of the Calbiochem 2000-2001 reagent catalog. (of record in previous action, herein referred to as Calbiochem)

The disclosure of Deggerdal et al. in view of Nargessi is discussed above. Deggerdal et al. in view of Nargessi does not disclose a method in which the detergent in the lysis buffer is a triton or tween detergent.

Calbiochem discloses various triton (octylphenoxypolyethoxyethanol, p. 541) and tween (polysorbate, polyoxyethylene sorbitan monolaurate, p. 546) nonionic detergents. These detergents are reasonably considered to fall within the scope of nonionic detergents included in the teaching of Deggerdal et al.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use triton or tween detergents in the lysis/binding solution of Deggerdal et al. in view of Nargessi. One of ordinary skill in the art would have been motivated to use these detergents because Deggerdal et al. already discloses that nonionic detergents in general can be used in the lysis buffer. One of ordinary skill in the art would reasonably have expected success because Deggerdal et al. teaches that any detergent can be used successfully, and selecting a particular detergent is well within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted June 4, 2009, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant's arguments are the same as those made against the rejection over Deggerdal et al. in view of Nargessi alone and are not found persuasive for the same reasons. Therefore the rejection is maintained.

Claims 28-29 and 55-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deggerdal et al. (PCT international publication WO96/18731, of record in previous office action) in view of Nargessi. (US patent 6855499, of record in previous action) as applied to claims 21-27, 30-32, 34-36, 38-40, 42, 43, 45-54, 57-59, 61-63, 65-67, and 69-71 above, and further in view of Heath et al. (PCT international publication WO99/39009, reference of record in previous action)

The disclosure of Deggerdal et al. in view of Nargessi is discussed above. Deggerdal et al. in view of Nargessi does not disclose a method in which the solid support is one or more polyesters.

Heath et al. discloses reagents and methods that incorporate a solid support for purifying DNA from samples. (p. 8, lines 8-11) The solid support can be a number of different materials including polyester. (p. 9, lines 12-15) These polyester solid supports are reasonably considered to fall within the scope of solid supports included in the teaching of Deggerdal et al.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use one or more polyesters as the solid supports in the method of

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Deggerdal et al. in view of Nargessi. One of ordinary skill in the art would have been motivated to use polyesters because Deggerdal et al. already discloses that various solid supports in general can be used to adsorb RNA and Heath et al. specifically discloses that polyester can adsorb nucleic acids. One of ordinary skill in the art would reasonably have expected success because Deggerdal et al. teaches that any solid support can be used successfully, and selecting a particular solid support is well within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted June 4, 2009, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that Heath et al. discloses only a method for purifying DNA. However, Heath et al. is only relied upon for the teaching of a polyester solid support. In view of the fact that Deggerdal et al. teaches that "polymeric materials" in general are useful as solid supports, and that DNA and RNA are similar nucleic acids that bind to a wide variety of similar solid supports, one of ordinary skill in the art would have recognized that polyester supports would work for binding RNA as well as DNA. Therefore the rejection is maintained.

### **Conclusion**

No claims are allowed in this application.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. OLSON whose telephone number is (571)272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/  
Examiner, Art Unit 1623  
8/7/2009

/Shaojia Anna Jiang/  
Supervisory Patent Examiner, Art Unit 1623